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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,478	12/14/2001	Robert A. Kay	1040-3	5212

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/017,478	<b>Applicant(s)</b> KAY ET AL.	
	<b>Examiner</b> Humera N. Sheikh	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5-15,17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-15,17 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

**Status of the Application**

Receipt of the Request for Continued Examination (RCE) under 37 CFR 1.114, the Preliminary Amendment and the Arguments/Remarks, all filed 03/29/04 is acknowledged.

Claims 1-3, 5-15, 17 and 18 are pending. Claims 1, 2, 5-8, 10, 11, 13-15, 17 and 18 have been amended. Claims 4 and 16 have been cancelled. Claims 1-3, 5-15, 17 and 18 are rejected.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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**Claims 1-3, 5-12, 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson *et al.* (US Pat. No. 6, 042,849) alone or in view of Hermelin *et al.* (US Pat. No. 6,258,846 B1).**

Richardson *et al.* teach an oral pharmaceutical composition comprising a dual layer combination tablet which is divided into two portions, one that is fully released into the stomach upon ingestion, and the other protected by an acid-resistant coating for release only in the intestine, whereby the intestine-release portion contains magnesium compounds/magnesium salts in combination with additional active agents and therapeutic substances, such as calcium and calcium salts (see reference column 6, line 62 through col. 11, line 55).

According to Richardson, upon oral ingestion of the tablet, agents of the immediate release layer dissolve rapidly in the stomach and are available for immediate absorption in the gastrointestinal tract. The polymer matrix of the controlled release layer, having been given an enteric coating in the granulation process with Eudragit, does not dissolve in the acid pH of the stomach, but remains intact until it passes to the upper part of the small intestine, where the enteric coating dissolves in the more alkaline environment of the intestine (col. 11, lines 25-33).

The magnesium is present either as magnesium salts, other magnesium compounds that release magnesium ions when ingested, or both. Magnesiums that can be used are, for example, magnesium citrate, magnesium acetate, magnesium ascorbate, magnesium oxide and the like (col. 6, line 62 through col. 7, line 39).

Richardson *et al.* teach that the compositions and dosage forms are useful for treating magnesium deficiencies, particularly in treating magnesium and metabolite deficiencies that are characteristic of specific segments of the population (col. 11, lines 44-47).

Additional active agents include calcium and calcium salts (about 400 mg to about 1200 mg) for the treatment of specific conditions, and can be optionally combined with vitamin D for treating conditions in which hypomagnesia adversely impacts calcium utilization (col. 7, line 62 through col. 8, line 1).

The pharmaceutical composition can be formulated into various suitable dosage forms, including tablets, (gelatin) capsules, a solution, a suspension and a powder (col. 4, lines 57-64); (claim 11).

Suitable enteric materials include fatty acid mixtures, methacrylic acid polymers and copolymers, ethyl cellulose, and cellulose acetate phthalates. Specific examples are methacrylic acid copolymers sold under the name Eudragit® (see col. 8, lines 42-65).

According to Richardson, acid-resistant films of these types are particularly useful in confining the release of the magnesium lactate and magnesium citrate to the post-gastric environment. Acid-resistant films can be applied as coatings over individual particles of the components of the formulation, with the coated particles then optionally compressed into tablets. An acid-resistant film can also be applied as a layer encasing an entire tablet or a portion of a tablet where each tablet is a single unit dosage form (col. 8, line 66 thru col. 9, line 17).

Example 2, at col. 10, line 35, demonstrates a dual layer tablet, comprising an immediate release layer that disintegrates in the stomach and a controlled release layer for release into the intestine.

Regarding the instantly claimed ratios and pH dissolution points, it appears that Richardson teaches similar amounts of calcium and magnesium which read on the applicants claimed ranges, but does not teach the instant pH dissolution amounts. It is deemed obvious to one of ordinary skill in that suitable amounts or percentages can be determined through routine or manipulative experimentation to arrive at the best possible outcome. In addition, there is no criticality seen in the instantly claimed ratios and percentages since Richardson explicitly teaches a magnesium/calcium dosage formulation comprising similar ingredients and components for the treatment of magnesium deficiencies as similarly desired by the applicant.

Richardson *et al.* teach a combination tablet in which the components are divided into two portions, one that is fully released into the stomach upon ingestion, and the other protected by an acid-resistant coating for release only in the intestine, optionally in a sustained-release manner, whereby the intestine-release portion contains magnesium compounds/magnesium salts such as magnesium oxide, magnesium citrate and magnesium acetate (col. 9, lines 35-54). Calcium and calcium salts are also taught for treating hypomagnesia (col. 7, line 62 – col. 8, line 1). While Richardson *et al.* teach delayed release, enterically-coated magnesium compounds that are delivered to the small intestine or post-gastric environment, Richardson *et al.* do not explicitly state that the calcium/ calcium salts are provided in an immediate release form. However, based

Art Unit: 1615

on the teachings of Richardson *et al.*, that the tablet components are divided into two portions, one fully released into the stomach and the other portion released only in the intestine, whereby magnesium is taught to be released in the intestine, one of ordinary skill in the art could conclude that the remaining calcium or calcium salts could be formulated for immediate release to provide complete release of calcium in the stomach, since magnesium is taught for release in the intestine. Demonstration of such skill is also evident from the reference of Hermelin *et al.* (see below).

**Hermelin *et al.*** teach an oral nutritional supplement composition that combines various forms of release that include immediate release, delayed released, controlled release, timed release, sustained release and combinations thereof wherein the composition comprises *calcium* present in an *immediate release* form (about 100 mg to about 2,500 mg) and *magnesium* present in a *controlled release* form (about 25 mg to about 400 mg) (see column 12, lines 16-62). Biologically acceptable calcium compounds include, calcium carbonate, calcium sulfate, calcium oxide, calcium gluconate, calcium hydroxide and the like. Biologically acceptable magnesium compounds include magnesium carbonate, magnesium oxide, magnesium hydroxide and magnesium sulfate (col. 15, lines 32-44). The dosage forms include tablets, such as multi-layer and bi-layer tablets, as well as capsules, powders, granules, etc. (col. 13, lines 4-19). Methacrylic acid co-polymers are disclosed at column 14, line 44. Plasticizers, lubricants, disintegrants, etc. are taught at col. 14, lines 32-39.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined teachings of Hermelin et al. within Richardson et al. because Hermelin et al. teaches a nutritional supplement composition comprising a combination of calcium, provided in an immediate release form and magnesium, provided in a controlled release form and similarly Richardson et al. teach a composition and dosage form useful for treating magnesium deficiencies comprising a combination tablet in which the components are divided into two portions, one that is fully released into the stomach upon ingestion, and the other protected by an acid-resistant coating for release only in the intestine, and also teaches magnesium in delayed release form for release into the intestines and calcium/calcium salts that can be released into the stomach (immediate release). The expected result would be an improved and beneficial pharmaceutical formulation that provides for an effective release of calcium and magnesium to treat magnesium-related disorders and deficiencies.

**Claims 13, 14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson et al. (US Pat. No. 6,042,849), as applied to claims 1-3, 5-12, 15 and 17 above and further in view of Hermelin et al. (US Pat. No. 6,258,846 B1).**

Richardson et al., as delineated above, teach an oral pharmaceutical composition comprising a dual layer combination tablet which is divided into two portions, one that is fully released into the stomach upon ingestion, and the other



Art Unit: 1615

protected by an acid-resistant coating for release only in the intestine, whereby the intestine-release portion contains magnesium compounds/magnesium salts in combination with additional active agents and therapeutic substances, such as calcium and calcium salts (see reference column 6, line 62 through col. 11, line 55).

Richardson *et al.* are deficient only in the sense that they do not teach the instant selection of calcium/calcium salts.

**Hermelin *et al.*** teach an oral nutritional supplement composition *calcium* present in an *immediate release* form (about 100 mg to about 2,500 mg) and *magnesium* present in a *controlled release* form (about 25 mg to about 400 mg) (see column 12, lines 16-62). Biologically acceptable calcium compounds include, *calcium carbonate*, *calcium sulfate*, *calcium oxide*, *calcium gluconate*, *calcium hydroxide*, *calcium citrate-malate* and the like (col. 15, lines 32-38). Biologically acceptable magnesium compounds are taught at col. 15, lines 39-44.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the combined teachings of Hermelin *et al.* within Richardson *et al.* because Hermelin *et al.* teach a nutritional supplement composition comprising a combination of various calcium compounds (i.e., *calcium carbonate*, *c. sulfate*, etc.) in immediate release form and magnesium provided in a controlled release form, and similarly Richardson *et al.* teach a composition and dosage form useful for treating magnesium deficiencies comprising a combination tablet of calcium (immediate release) and magnesium (delayed release). The expected result would be an effective dosage

Art Unit: 1615

formulation comprising essential supplements of calcium in combination with magnesium to provide for enhanced magnesium absorption and intake, as similarly desired by the Applicant.

Furthermore, regarding the instant combination of magnesium with calcium or phosphate, the examiner notes, that for the treatment or correction of mineral or vitamin deficiencies, nutrients must work synergistically. There is a cooperative action between certain vitamins and minerals, which work as catalysts, promoting the absorption and assimilation of other vitamins and minerals. Correction of a deficiency of one vitamin or mineral requires the addition of others, not simply replacement of the one in which you are deficient. It is realized that with magnesium deficiency, supplements needed for assimilation would be: *calcium*, phosphorous, potassium, vitamins C and D and vitamin B<sub>6</sub>, for example. Therefore, there are no unexpected results that accrue from the applicant's use of the claimed combination.

Prior art not relied upon, made of record and deemed relevant by Examiner:

US Patent No. 5,811,126 Krishnamurthy *et al.* (09/1998)

US Patent No. 4,339,428 Tencza (07/1982)

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***Response to Arguments***

Applicant's arguments filed 03/29/04 have been fully considered but they are not persuasive.

Firstly, the Applicant argued regarding the 35 U.S.C. §103(a) rejection of claims 1-12 and 15-17 over Richardson et al. (US '849) stating, "The dual layer combination tablet combines calcium and magnesium so that they are simultaneously released into the body. Richardson does not disclose the sequential release of first calcium and then magnesium. The use of a time release component to limit the interaction of calcium with magnesium is neither taught nor suggested by Richardson."

These arguments have been fully considered, but were not found to be persuasive. Richardson teaches a dual layer tablet wherein the components are divided into two portions, one that is fully released into the stomach upon ingestion, and the other protected by an acid-resistant coating for release only in the intestine, and optionally in a sustained-release manner over a period of time (col. 9, lines 35-41). Richardson teaches that a delayed, post-gastric, prolonged release of the active ingredients in the small intestine can be achieved by encasing active agents or by encasing hydrophilic, water-swelling polymers containing the active agents, in an enteric (acid-resistant) film. Richardson states that acid-resistant films (i.e., methacrylic acid polymers, cellulose acetate phthalates) are particularly useful in confining the release of the magnesium lactate and magnesium citrate to the post-gastric environment. The 'controlled' or 'sustained' or 'time-release' delivery are equated to describe the type of active agent delivery that occurs when the active agent is released

from a delivery vehicle at an ascertainable and manipulatable rate over a period of time, rather than being dispersed immediately upon entry into the digestive tract or upon contact with gastric fluid. Richardson's formulation provides a formulation divided into two components, of which one portion is released into the stomach and the other portion to be released into the intestines. Since the magnesium compounds are provided in delayed release form for release into the intestines (col. 8-9), one of ordinary skill in the art can conclude that the calcium/calcium salts would be formulated for release into the stomach or immediate release. Thus, the release rates for calcium and magnesium would be considered sequential release, rather than simultaneous release, as asserted by Applicant.

Secondly, the Applicant argued, "Richardson does not disclose that calcium is included in either the first or second layer of the dual layer tablet, nor does he teach a preference for calcium in either the immediate release layer or in the delayed release layer."

These arguments have been fully considered, but were not found to be persuasive. According to Richardson, upon oral ingestion of the tablet, agents of the immediate release layer dissolve rapidly in the stomach and are available for immediate absorption in the gastrointestinal tract. Calcium and calcium salts are taught as additional active agents. Richardson states that a slower, more sustained release of the active agents can be achieved by placing the active agents in one or more delivery vehicles that inherently retard the release rate. The applicants argument that a preference for calcium in the immediate or delayed release layer is not taught, is therefore not persuasive since Richardson clearly teaches calcium and its salts in

combination with magnesium compounds wherein the magnesium compounds are provided in delayed release forms and contain enteric coatings for release only in the intestine. Hence, calcium would be construed as being contained in the immediate release layer of the tablet. The art clearly teaches confining the release of magnesium compounds to the post-gastric environment.

Next, the Applicant argued, "There is no teaching nor suggestion in Richardson that calcium can be in a layer of a dual layer tablet without being combined with magnesium. Richardson does not teach a formulation or a two-layer tablet containing calcium and magnesium where the two components are not simultaneously released into the body. Moreover, the '849 patent does not teach the benefits of separating the calcium component from the magnesium component as required by the present claims."

These arguments have been fully considered, but were not found to be persuasive. Richardson exemplifies the combination of magnesium compounds with Vitamin E and does not explicitly exemplify magnesium with a calcium component in the examples. However, Richardson clearly discloses the use of calcium and its salts as additional active agents in the formulation, whereby magnesium compounds are confined in terms of sustained or controlled release rates for delivery into the intestine. Richardson does not state that the calcium be contained in the same layer as the magnesium component, and therefore one would conclude that the calcium component can be contained in a separate and distinct layer than that of the magnesium component. Furthermore, it is of no moment that the prior art explicitly teach the benefits of separating the calcium from the magnesium component, merely that the prior art teach and recognize the presence of similar ingredients, in this case, magnesium and calcium components, in a similar functional manner as intended by the applicants is

Art Unit: 1615

sufficient. Richardson's focus is on the teaching that the magnesium components are confined to releasing at delayed or sustained release rates to the post-gastric environment.

The Applicant argued, "Richardson does not teach that the interaction of calcium with magnesium prevents the efficient absorption of magnesium, nor does Richardson teach formulations containing calcium and magnesium should include a means for limiting their interaction."

These arguments were thoroughly considered, but were not persuasive. Richardson teaches a dual layer tablet, one portion, which fully releases its components in the stomach upon ingestion and the other protected by an acid-resistant coating for release only in the intestine. The tablet contains magnesium and calcium components. One of ordinary skill in this art would be well aware of suitable combinations of interactive agents to achieve effective results without contributing to adverse or detrimental effects.

Next, the Applicant argued, "The Office Action states that Richardson discloses a formulation with a delayed release of both magnesium and calcium in the intestine. Unlike Richardson, the present composition does not delay release of both magnesium and calcium in the intestine."

These arguments have been considered, but were not found to be persuasive. The examiners' recitation of magnesium compounds/salts in combination with additional active agents was not to be construed as both the magnesium and calcium components being delayed release, as interpreted by the applicant. Rather, it was pointed out that Richardson along with magnesium components, also teaches calcium and its salts, wherein the tablet is divided into two portions, one that is fully released into the stomach upon ingestion and the other protected by an acid-resistant coating for release only in

the intestine. Nowhere in the Richardson patent does it teach that the calcium component is contained in a delayed release form, hence leading one to conclude calcium is in immediate release form. The objective of Richardson is to provide advantages in terms of controlling and sustaining the release of magnesium in locations along the digestive tract wherein magnesium will have its greatest effectiveness as a therapeutic agent, thus improving the control over the clinical bioavailability of magnesium.

The Applicant then argued, "Richardson teaches that additional active agents are optionally included in the formulations and that examples of additional active agents are calcium and calcium salts. Thus Richardson only teaches that calcium can be 'included in the formulations'.

This argument was not found persuasive. The teaching by Richardson that additional active agents are *optional*, of which calcium and calcium salts are included, is a positive teaching that cannot be ignored in the art. The term 'optional' active agent clearly provides an individual the preference of choosing to include the active agent, based on the desired or intended purpose at hand. In this instance, calcium and calcium salts can be added to the formulation in combination with magnesium compounds.

The Applicant argued over the 35 USC 103(a) rejection of claims 13, 14 and 18 over the '849 patent in view of Krishnamurthy (US '126) or Tencza (US '428) stating, "Krishnamurthy teaches mixing calcium and magnesium together and does not teach nor suggest preventing them from interacting when released in the body. Krishnamurthy when combined with Richardson, does not make the present invention obvious since neither reference discloses a composition which releases calcium in the stomach and releases magnesium in the intestine in a manner that avoids

substantial interaction between the two components.” It was also argued, “Tencza discloses a combination of calcium and magnesium which is similar to Richardson and Krishnamurthy, but different from the present invention. Tencza's combination fails to teach the composition of the present invention which has separate and not combined calcium and magnesium components. The formulations of Tencza do not have a delay release mechanism, which prevents the calcium component and the magnesium component from releasing at the same time and interacting. Richardson, Krishnamurthy and Tencza, either alone or in combination, fail to disclose the sequential release of calcium and magnesium. Moreover, there is no teaching or suggestion in any of these references that would make the present invention obvious to one of ordinary skill in the art.”

These arguments have been considered, but were not found to be persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Richardson teaches an oral pharmaceutical composition comprising a dual layer combination tablet which is divided into two portions, one that is fully released into the stomach upon ingestion, and the other protected by an acid-resistant coating for release only in the intestine, whereby the intestine-release portion contains magnesium compounds/magnesium salts and wherein the formulation additionally contains active agents and therapeutic substances, such as calcium and calcium salts. Richardson is lacking only in the sense that he does not explicitly teach the instant selection of



calcium salts. Krishnamurthy and Tencza, were both solely relied upon for the generic teaching that it is well known to use particular calcium salts, as those instantly claimed, in a formulation along with magnesium compounds. Krishnamurthy and Tencza were not relied upon to demonstrate the sequential release of calcium and magnesium, since Richardson has initially met that requirement as stated above. Both Krishnamurthy and Tencza teach various calcium forms as recited in applicant's claims 13, 14 and 18. The prior art (Richardson) teaches a formulation for controlling or sustaining the release of magnesium into a post-gastric environment and release only in the intestine. The secondary references (Krishnamurthy, Tencza) recognize and teach the known calcium components as those instantly recited.

The Examiner points out that the Krishnamurthy and Tencza references have now been cited as relevant art of record. The current Office Action rejects Claims 13, 14 and 18 over Richardson et al. in view of *Hermelin et al.*

Richardson *et al.* teach an oral pharmaceutical composition comprising a dual layer combination tablet which is divided into two portions, one that is fully released into the stomach upon ingestion, and the other protected by an acid-resistant coating for release only in the intestine, whereby the intestine-release portion contains magnesium compounds/magnesium salts in combination with additional active agents and therapeutic substances, such as calcium and calcium salts. Richardson is lacking only in the sense that he does not teach the selective calcium salts/compounds. Hermelin et al. is relied upon to resolve this only deficiency of Richardson et al. by teaching a combination formulation of calcium (immediate release) and magnesium (controlled

Art Unit: 1615

release), whereby various calcium compounds, such as *calcium carbonate*, *calcium sulfate*, *calcium oxide*, *calcium gluconate*, *calcium hydroxide*, *calcium citrate-malate* and the like are taught (see col. 15, lines 32-38). Hence, ample motivation is provided by the prior art to use the combination of ingredients for the purpose of obtaining effective and beneficial results for the treatment of magnesium-related disorders and deficiencies, as similarly desired by the Applicant. Since the prior art teaches a similar formulation for the same field of endeavor, comprising similar ingredients and for an equivalent intended purpose as the Applicant, the instant invention is rendered obvious and unpatentable over the prior art of record.

### Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays from 8:00 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

*hns / x.s.*

July 12, 2004

THURMAN v. PAGE  
SUPERVISORY EX-1600  
MINER